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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,173	01/14/2002	Michela Seveso	P24376 USA	5272

7590

07/12/2006

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EXAMINER
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ANGELL, JON E

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/743,173

Applicant(s)

SEVESO ET AL.

Examiner

Jon Eric Angell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,32 and 43-65 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1 43-65 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

This Action is in response to the communication filed on 4/18/2006.

The amendment filed 4/18/2006 is acknowledged and has been entered.

Claim 12 has been cancelled. New claims 43-65 have been added.

Claims 1, 2, 32 and 43-65 are currently pending in the application and are addressed herein.

Claims 2 and 32 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) for the reasons of record indicated in the previous Office Action (1/13/2006). Applicant timely traversed the restriction (election) requirement in the reply filed on 10/13/2005.

The amendment filed April 18, 2006 adds new claims that are considered to be drawn to inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1 for the reasons indicated herein.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 43-65, drawn to a method for enhancing the intracellular delivery of a nucleic acid-based drug in a mammal comprising administering to the mammal, in combination with the nucleic acid-based drug, an enhancer wherein the enhancer is caprylic acid or an ether, salt or anionic derivative thereof.

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Group II, claim(s) 1, 43, 46-65 drawn to A method for enhancing the intracellular delivery of a nucleic acid-based drug in a mammal comprising administering to the mammal, in combination with the nucleic acid-based drug, an enhancer wherein the enhancer is nonanoic acid or an ether, salt or anionic derivative thereof.

Group III, claim(s) 1, 43-65 drawn to A method for enhancing the intracellular delivery of a nucleic acid-based drug in a mammal comprising administering to the mammal, in combination with the nucleic acid-based drug, an enhancer wherein the enhancer is capric acid or an ether, salt or anionic derivative thereof.

Upon election of one of groups I-III, Applicants are also required to further elect one of the following subgroups inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1

1) oligonucleotide, including a gene coding for an RNA that functions in an antisense capacity and a gene coding for a ribozyme

2) plasmid DNA, including a gene coding for a protein

3) ribozyme, including a gene coding for a ribozyme

If subgroup 1) oligonucleotide is elected, Applicants are also required to further elect one of the following additional subgroups inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1

a) antisense oligonucleotide including a gene coding for an RNA that functions in an antisense capacity

b) triplex forming oligonucleotide

c) oligonucleotide which acts as an adjuvant

The inventions listed as Groups I-III as well as subgroups 1-3 and further subgroups a-c do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: in order for the invention to relate to a single general inventive concept, they must be linked by a "special" technical feature.

PCT rule 13.2 states, "The expression 'special technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." In other words, if the technical feature which links the inventions is not novel (i.e., it does not make a contribution over the prior art), then it is not special.

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In the instant case, claim 1 is a broad claim which links all of the inventions. Therefore, claim 1 is considered the technical feature that links all of the inventions (including all subgroups). Since claim 1 does not make a contribution over the prior art in view of WO 99/01579 (Teng et al.) and/or WO 96/05218 (Whitaker et al.), both previously of record, it is not a special technical feature. Accordingly, the Inventions (as well as all subgroups) are not linked by a special technical feature and the Inventions do not relate to a single general inventive concept.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of modified oligonucleotides are as follows:

- i) oligonucleotide having a modified backbone chemistry,
- ii) an oligonucleotide having a modified sugar or terminal group,
- iii) a chimeric oligonucleotide comprised of nucleotides of different chemistries,
- iv) an oligonucleotide having MOE chemistry

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1, 43-65.

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The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: they oligonucleotide modifications are well known in the prior art (e.g., see U.S. Patent 5,801,154 (Barracchini et al.)).

A telephone call was made to Jonathan Dermott on 7/9/2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

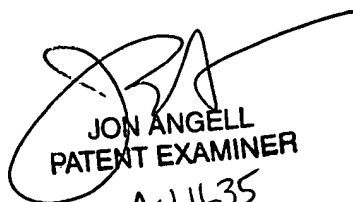
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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
JON ANGELL  
PATENT EXAMINER  
AU 1635